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PATENT

ATTORNEY DOCKET: 59866.000002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number :

09/546,573

Confirmation No.:

3408

**Applicant** 

Mads HOLTEN-ANDERSEN, et al.

Filed

: April 10, 2000

Title

TISSUE INHIBITOR OF MATRIX METALLOPROTEINASES

TYPE-1(TIMP-1) AS A CANCER MARKER

TC/Art Unit

: 1643

Examiner:

: S. L. Rawlings

Docket No.

59866.000002

Customer No.

21967

## MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## <u>INFORMATION DISCLOSURE STATEMENT</u>

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, applicants submit attached Form PTO-SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office in the above-captioned application.

Applicant wishes to inform the Examiner of the existence of the following copending U.S. patent application:

U.S. Patent Application No. 10/470,658 filed March 28, 2005, entitled "A Method for Detecting, Screening, and /or Monitoring a Cancer in an Individual" (attorney docket number: 59866.00005). A copy of this U.S. Patent Application as filed is enclosed.

Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

For the convenience of the Examiner in considering the cited references, a copy of each of the cited references is enclosed with this communication. In considering the cited

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references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited references obtained by the associated individuals, or were made thereon during the study of the references by the associated individuals.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP 609 are respectfully requested.

In accordance with 37 C.F.R. § 1.97(b), this Information Disclosure Statement is believed to be submitted prior to issuance of a first Office Action on the merits, or a Notice of Allowance. Therefore, it is respectfully submitted that no fee is required for consideration of this information. However, in the event any fee is deemed necessary, the Commissioner is authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

**HUNTON & WILLIAMS LLP** 

Dated: February 1, 2006

By:

tanislaus Aksman

Registration No. 28,562

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PTO/SB/08B (08/03) (modified) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

09/546,573

Substitute for form 1449A/PTO INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

(use as many sheets as necessary)

Filing Date April 10, 2000 First Named Inventor Mads HOLTEN-ANDERSEN, et al. Art Unit 1643 Examiner Name S. L. Rawlings

Sheet 1 of 3 Attorney Docket Number 59866.000002

Application Number

*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US- 10/470,658	03-28-2005	Lasse L. HESSEL, et al.	
		US-			

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO/SB/08B (08/03) (modified) U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Substitute for form 1449/PTO Application Number 09/546.573 Filing Date April 10, 2000 INFORMATION DISCLOSURE Mads HOLTEN-ANDERSEN, et STATEMENT BY APPLICANT First Named Inventor (use as many sheets as necessary) Art Unit 1643 Examiner Name S. L. Rawlings Sheet 2 of 3 Attorney Docket Number 59866.000002 OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the TRANSLATION \*Examiner item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue Initials No. number(s), publisher, city and/or country where published NO 2. Agency for Health Care Policy and Research, "Colorectal Cancer Screening: Summary", Evidence Report: Number 1. AHCPR Publ. No. 97-0302, pg. 1-4. П 3. Aznavoorian S. et al., "Molecular Aspects of Tumor Cell Invasion and Metastasis", Cancer, 15, 71(4), pg. 1368-1383, 1993. 4. Balk, S. P. et al., "Biology of Neoplasia, Biology of Prostate-Specific Antigen", Journal of Clinical Oncology, 21 (2), pg. 383-391, 2003. 5. Benson, A. B., et al., "ASCO Special Article - 2000 Update of American Society Colorectal Cancer Surveillance Guidelines", Journal of Clinical Oncology, 18(20), pg. 3586-3588, October 15, 2000. П 6. Birkedal-Hansen, "Role of Matrix Metlloproteinases in Human Periodontal Diseases", J. Periodontal., pg. 474-484, May 1993. 7. Breimer, D. D., et al., "Saliva: A Fluid for Measuring Drug Concentrations", Pharmacy П Internation, 1, pg. 9-11, 1980. 8. Khokha, R. et al., "AntisenseRNA-Induced Reduction in Murine TIMP Levels Confers Oncogenicity on Swiss 3T3 Cells", Science, 243, pg. 947-950, February 17, 1989. 9. Kleiner, et al., "Stability Analysis of Latent and Active 72-kDa Type IV Collagenase: The Role of Tissue Inhibitor of Metalloproteinases-2 (TIMP-2)", Biochemistry, 32, pg. 1583-1592, 1993. 10. Lovgren, J., et al., "Measurement of Prostate-Specific Antigen and Human Glandular Kallikrein 2 in Different Body Fluids", J. Andrology, 20, pg. 348-355, 1999. 11. Remacle, A. et al., "High Levels of TIMP-2 Correlate with Adverse Prognosis in Breast  $\Box$ Cancer", Int. J. Cancer, 89, pp. 118-121, 2000. 12. Stetler-Stevenson WG et al., "Matrix Metalloproteinases and Tumor Invasion: From Correlation and Causality to the Clinic", Semin. Cancer. Biol., 7, pp. 147-154, 1996.

**EXAMINER SIGNATURE** 

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitu	ite for	form 1449/PTO	Application Number	09/546,573			
INI	50I	RMATION DISCLOSURE	Filing Date	April 10, 2000  Mads HOLTEN-ANDERSEN, e			
		EMENT BY APPLICANT	First Named Inventor			et	
(use as many sheets as necessary)  Sheet 3 of 3			Art Unit 1643				
			Examiner Name	S. L. Rawlings			
			Attorney Docket Number	59866.000002			
		OTHER DOCUMENTS - NON	-PATENT LITERATURE	DOCUMENTS			
*Examiner Cite Initials No.		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			TRANSI YES	LATION	
	13.						
	14.	Vignola et al., "Sputum Metalloproteinase-9/Tissue Inhibitor of Metalloproteinase-1 Rat Correlates with Airflow Obstruction in Asthma and Chronic Bronchitis", Am. J. Respir. Cr Care Med., 158, pp. 1945-1950, 1998.					
:	15.	Vining, R. and McGinley, RA, "Hormones in Saliva", Critical Reviews in Clinical Laboratory Science, 23, pp. 95-146, 1985.					
	16.	Welgus HG et al., "Human Skin Fibroblast Collagenase Interaction with Substrate and Inhibitor", Coll. Relat. Res., 5, pp. 167-179, 1985.					
	17.	Wolff, K. et al., Hay. A., "Methadone in S	Saliva", Clinical Chemistry, 37,	pp. 1297-1298, 1991.			
	18.	Garrett, C. Durkan et al., "Prognostic Significance of Matrix Metalloproteinase-1 and Tissue Inhibitor of Metalloproteinase-1 in Voided Urine Samples from Patients with Transitional Cell Carcinoma of the Bladder", Clin. Cancer Res., 7, pp. 3450-3456, Nov. 2001.					
i	Birkedal-Hansen, H. et al., "Matrix Metalloproteinases: A Review", Crit. Rev. Oral. Bio Med., 4(2), pp 197-250, 1993.						
	20. McCarthy K. et al., "High Levels of Tissue Inhibitor of Metalloproteinase-1 Predict Po Outcome in Patients with Breast Cancer", Int. J. Cancer, 84, pp. 44-48, 1999.						
EXAMINER SIGNATURE DATE CONSIDERED							
*EXAMI citation	NER:	Initial if reference considered, whether or in conformance and not considered. Include	not citation is in conformance copy of this form with next com	with MPEP 609. Draw li	ne thro	ough	